Cham'ge?
Karibu Kericho
Capitalizing Upon Local Capacity and Experience for Clinical Research Data Management in Resource Limiting Settings: the Kericho “CLADE” Study

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Background

- With the growing number of clinical trials conducted in sub-Saharan Africa, the need and obligation exists to develop local capacity and expertise to design, implement and analyze research.
- Quality data collection, management and analysis is essential for all research.
- Data collected locally, entered, cleaned and analyzed provides more efficient use of resources and timing for such trials.
Objectives

- To describe the processes and lessons learned based upon local data management in the Kericho “CLADE” Study

- The Kericho “CLADE” Study
  - Clinic-based ART Diagnostic Evaluation
  - An unblinded, randomized, clinical trial evaluating the superiority and cost-effectiveness of two Ministry of Health antiretroviral therapy (ART) diagnostic approaches
  - 820 adults starting ART followed for 18 months over a 30 month period (12 month accrual)
  - Conducted at 7 HIV clinics in the rural, southern Rift Valley Province and Lake Victoria border of Kenya
CLADE Study Sites

- 7 tertiary, district level HIV clinics
  - 5 MoH
  - 2 Faith-based
- Majority staffed by Clinical Officers
- Non-research setting
- Under the US President’s Emergency Plan for AIDS Relief (PEPFAR) program
Data Management

- Database (Microsoft SQL) developed locally with visual basic forms/data entry screens
- Case report forms (CRFs) developed to mirror the clinic encounter forms for easy data extraction
- Data extraction and CRF entry by site Study Coordinators
- Data entry at each site by study data clerks with de-identified data transported weekly by password protected laptop and uploaded to the central database
- Data queries built into the SQL database to capture study endpoints and generate patient summaries
Data Processes

- Weekly data upload
- Monthly data calls
- Ongoing data management
- Data Reports and Queries
- Volunteer visits and evaluations
- Local data extraction, paper CRF
- Site data entry to mobile laptop
- Ongoing QA/QC by study coordinator/s
- Query resolution

EmpiriStat, US MHRP

KEMRI/WRP IT

CLADE Study Sites

Maryland, USA

Kericho, Kenya

Rural Kenya

Cell phone randomization
Data Monitoring

- Reports and summaries generated weekly for study team with monthly teleconferences

- Formal reports generated as part of Data Monitoring Committee (DMC) bi-annual reviews including:
  - Accrual Patterns
  - Demographics
  - Safety Including Morbidity and Mortality
  - Primary and Secondary Endpoints
  - Data Completeness and Quality Assurance

- Data including CRFs and summaries reviewed by an independent monitoring group bi-annually
Data Analyses

- Data analysis plan developed by study statistician in consultation with study Principal Investigators

- All analyses to be done in Kenya
  - Lead by CLADE Data Manager
  - PC SAS v8.0 (SAS Institute inc. USA)
  - Close consultative guidance, review, and sign-off by Study Statistician
Mentorship

- Secondary study objective – development local expertise in data management and analyses

- Data Manager (BS Computer Science) supported by study in ongoing Master of Medical Statistics program with final masters thesis based upon CLADE

- Key mentorship
  - EmpiriStat (Dr. Nicole Close)
  - KEMRI/WRP Leadership and Co-PIs

- Site study nurses mentored on research by study coordinator and investigators
Challenges & Achievements

- **Challenges**
  - Travel distance between CRC and study sites
  - Capacity & Infrastructure at busy, resource-constrained clinics (space, staff turnover, research experience)
  - Query response times

- **Achievements**
  - Successful, novel randomization methods
  - Clinic extraction and CRF management
  - Overall data quality and accuracy
KDH Data entry
Summary

- Identifying staff with Data management experience, Computer Science/Information Technology and programming / statistics skills is critical in developing clinical research data systems.

- External Staff experienced with data entry and support will facilitate local capacity development.

- Including expert consultants early and available (both scheduled and unscheduled) is critical for success.

- Local capacity exists and can support development of data components for prospective clinical trials that are monitored for adherence to Good Clinical Practice and should be utilized at increasing frequencies.
# Acknowledgements

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| MHRP-Rockville    |                          |                 |
| Nelson Michael    | Merlin Robb              |                 |
| Mary Marovich     | Tiffany Hamm             |                 |
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